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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,237	05/21/1999	HIDENORI OHKI	0018-1052-0P	5890

22850 7590 05/23/2003

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/308,237

Applicant(s)

Ohki et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Mar 25, 2003

2a) ☒ This action is **FINAL**.

2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 47-53 and 56-82 is/are pending in the application.

4a) Of the above, claim(s) 48, 49, 51, 52, 56-70, 72, 73, and 75-82 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 47, 50, and 71 is/are rejected.

7) ☒ Claim(s) 53 and 74 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Amendment filed 03/25/2003 is acknowledged. Claims 68-82, drawn to compositions, are added. Claims 47-53, 56-82 are pending.

2. As per election of species, as the species addressed in the previous Office action are no longer claimed, the examination was extended to species where R_1 is benzoyl substituted with piperidyl having piperidyl having cyclo(lower)alkyl. Claims 47, 50, 71 read on thus elected species. Claims 48, 49, 51, 52, 56-63, 68-70, 72, 73, 75-82 are withdrawn from consideration and are not addressed in art rejections as drawn to non-elected species.

As the claims drawn to products remain to stand rejected, claims 64-67, drawn to methods of making and using, remain withdrawn from consideration, as being drawn to previously non-elected groups¹.

¹As indicated in Office action mailed 01/22/02, a cursory look at claims drawn to method of use indicated that the claims will be subject of the scope of enablement rejection as the only experimental data present in the specification (p. 30-32) demonstrate effect on only two microorganisms, *Candida* and *Pneumocystis*.

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Claim Rejections - 35 USC § 103

3. Claims 47,50,71 are rejected under 35 U.S.C. 103(a) as obvious over Ohki et al (WO 96/11210)

Ohki et al teach cyclic peptides of formula 1 which have antifungal activity and pharmaceutical compositions thereof. Radical R1 in the referenced compounds (which corresponds to R1 in the claimed compounds) can be benzoyl substituted with piperidyl having piperidyl. See example 67, p. 177. Said example does not demonstrate last piperidyl having cyclo(lower)alkyl moiety. However, the reference teaches that cyclo(lower)alkyl moiety is the preferred substituents for R1, wherein R1 is aroyl substituted with heterocyclic group having heterocyclic (i.e., in the instant case, "aroyl substituted with heterocyclic group having heterocyclic group" is benzoyl substituted with piperidyl having piperidyl). See p. 25, lines 16-26. Therefore, it would have been *prima facie* obvious to one skilled in the art to be motivated to make such a modification of piperidyl group of the example 67 so as to obtain another preferred compound with the activity disclosed in WO 96/11210.

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4. Claims 53 and 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703)

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305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 20, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

